FY 2008 NIH Research Priorities for Women's Health

The mission of the Office of Research on Women's Health (ORWH) is to stimulate and encourage meritorious research on women's health, including the role of sex and gender in health and disease. Each year, the *ad hoc* Research Subcommittee of the Coordinating Committee on Research on Women's Health (CCRWH), composed of representatives from the NIH institutes and centers, considers continuing gaps in knowledge, and emerging scientific opportunities for current research priorities in women's health. The Subcommittee's recommendations are reviewed and approved by the CCRWH and the Advisory Committee on Research on Women's Health (ACRWH).

Research opportunities are described in terms of overarching themes, special emphasis areas, and areas of research interest. The priorities signify approaches and areas for which there is a need to stimulate and encourage research on women's health, or sex/gender factors, and the advancement of women in biomedical research careers. These research priorities are not an exclusive list of research areas important to women's health; therefore other innovative or significant research areas should also be considered.

I. OVERARCHING THEMES

The following four overarching themes are important for addressing research on women's health: *Lifespan, Sex/Gender Determinants, Health Disparities/Differences and Diversity, and Interdisciplinary Research.*

Lifespan: The health of girls and women is affected by developmental, physiological, and psychological age. Women's lives are marked by a continuum from intrauterine life to the elderly years: infancy, childhood and adolescence, menarche, reproductive life, the menopausal transition, postmenopausal years, the elderly, and frail elderly. Many women's lives and health status are also influenced by factors such as work inside and outside the home, care-giving such as childcare and elder care responsibilities, reproductive status, marital status, and chronic illness. Each of these may influence health, disease, lifestyle and treatment choices, and response to therapy. Researchers should consider these variables in designing studies related to women's health.

Sex/Gender Determinants: Women are characterized by both sex and gender as highlighted in the *Agenda for Research in Women's Health for the 21st Century* and the Institute of Medicine report, entitled *Exploring the Biological Contributions to Human Health: Does Sex Matter*? In this context, the term sex refers to being male or female according to reproductive organs and functions assigned by chromosomal complement. Sex factors that contribute to the biological differences include chromosomes, reproduction, and hormones. Gender refers to socially defined and derived expectations and roles rooted in biology and shaped by environment and experience. Gender and sex are important considerations in many areas of research, including basic biological, psychological, social, and behavioral studies. Consideration of these variables may be critical to the accurate interpretation and validation of research affecting aspects of

women's health. These variables determine how health or disease processes may differ among women or between men and women.

Health Disparities/Differences and Diversity: Women are disproportionately affected by some conditions and diseases in terms of incidence, diagnosis, course, and response to treatment. Some populations of women may be at higher risk for adverse disease outcomes because of factors such as: biology, genes, culture, education, effects of poverty, access to care, quality of care, and access to opportunities for inclusion as research subjects in clinical trials and studies. Thus, clinical research should include, but not be limited to, population-specific characteristics such as cultural diversity, environmental exposures, race/ethnicity, immigrant status, rural or inner city (urban) residency status, effects of poverty or low socioeconomic status, sexual orientation, and physical or mental disabilities.

Interdisciplinary Research: With increasing understanding of the inter-relatedness and complexity of disease, the nature of scientific investigation is shifting to an interdisciplinary, collaborative approach. Advances in women's health can be better achieved by promoting partnerships across disciplines. Interdisciplinary approaches can integrate knowledge from multiple specialties and disciplines, thus enhancing the likelihood of defining underlying pathologic processes. Collaborations among researchers in academia, private industry, and federal settings can provide access to the latest scientific tools and technologies and expertise for women's health research.

II. SPECIAL EMPHASIS AREAS

The NIH is especially interested in fostering research in women's health in the high priority areas of prevention and treatment, and the biological and behavioral basis of sex and gender differences.

Prevention and Treatment

Increased investigation into methods to prevent conditions and diseases, or to better treat them, can result in significant improvements in the quality and length of women's lives. Prevention research spans the continuum from the most basic biological studies to examine the basis of both risk and protective factors and behaviors across the lifespan, as well as the interventions to improve them. This includes a focus on communication of wellness and healthy behaviors in health care provider-patient interactions and in public awareness campaigns. Examples of needed prevention and treatment research studies in women's health include, but are not limited to:

- Research in early detection and treatment, including the development of novel tools to identify and validate biomarkers, including genetic polymorphisms, and RNA expression profiles and functional and morphological brain changes in relation to disease risk, pathogenesis, progression, and to assess their clinical utility for disease prevention;

- Examinations of environmental and social determinants involved in disease initiation and progression will be helpful in developing prevention and treatment strategies;
- Studies of the impact on health of factors such as alcohol and drug use or abuse, diet, eating disorders, exercise, hormones, obesity, occupations, sex practices, sleep quality, tobacco, toxin exposures, the use of dietary supplements, violence or trauma weight patterns;
- Development of multi-modal approaches to chronic diseases that contribute significantly to public health disability burden. Examples include addictions, brain injury, cancer, chronic multi-systemic diseases, coronary artery disease, diabetes, neurodegenerative disorders such as Alzheimer's disease, musculoskeletal disorders, obesity, pain syndromes, sexually transmitted diseases, and stroke; and
- Studies of the effect of biological, behavioral, cultural, economic, environmental, and social factors on susceptibility to, or protection from, disease and response to treatment, and where appropriate sub-set analyses can facilitate personalized medicine.

Biological and Behavioral Basis of Sex and Gender Differences

While there has been much research to identify the function of cellular pathways and genes, research on the effects of sex as a modifier of cellular and gene function is under-investigated. Systemic and cellular modeling of the influence of sex differences in biological pathways and systems is needed, including, but not limited to:

- Mechanisms of sexual dimorphism in gene expression and cellular and signaling pathways in healthy women, including the impact of puberty, the menstrual cycle, pregnancy, and menopause;
- Sexual dimorphism in expression and function of genes, genetic polymorphisms, and gene defects in the risk factors, etiology, severity, and response to treatment of diseases;
- Genetic, molecular and cellular basis of action of pharmacologic agents in women, including differential effects between males and females; and
- Using basic, translational, behavioral, and clinical research approaches, sex and gender differences in the prevention, pathogenesis, course, and response to treatment.

III. AREAS OF RESEARCH INTEREST

Basic, clinical and translational research should be considered in addressing priority areas in women's health research. Some examples may include, but are not limited to:

- **Diseases and Conditions that Affect Women.** Investigate the pathogenesis and develop preventive and therapeutic interventions for acute and chronic diseases and disorders that affect women including, but not limited to, addiction,

autoimmunity, cardiovascular diseases, endocrine, gastrointestinal, inflammatory, metabolic, musculoskeletal, neurological, ophthalmic, oral, psychiatric, reproductive, and urologic diseases.

- **Basic and Clinical Research Methodology.** Develop clinical trial methodology, including novel recruitment strategies, standardized outcome strategies, and statistical analyses that address ethical and study design issues specific to studies of women. Develop new methodologies for animal model studies of the normal development of women, and their health and diseases, including female animal models. Encourage methodological studies related to the conceptualization, distinction and detection of sex and gender differences in basic and clinical biomedical research. Encourage collaborations between basic scientists and clinicians to identify and test potentially relevant therapeutic approaches.
- **Quality of Life.** Elucidate the biologic and behavioral factors that may affect women's quality of life, especially elderly women. Develop approaches to management of disease and promotion of wellness that are unique for women, their families and their communities.
- **Research Collaborations and Partnerships.** Enhance trans-NIH, multi-HHS agency, public-private partnerships, public information partnerships, community-based participatory research in women's health and career development which promote community-based health communication.
- **Career Development and Advancement of Girls and Women in Science.** Identify and explore factors that affect the selection and advancement of women's careers in biomedical sciences; test the effectiveness of novel education programs directed at increasing the participation of girls and women in science and math education; and design and evaluate new approaches to reduce barriers to the sustained advancement and effective mentoring of women to senior and leadership positions in science.

FY 2008 *ad hoc* Research Subcommittee of the NIH Coordinating Committee on Research on Women's Health

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